

## **Package leaflet: Information for the patient**

### **PENNSAID 16 mg/ml cutaneous solution** diclofenac sodium

#### **[For RX only]**

**Read all of this leaflet carefully before you start using this medicine because it contains important information for you.**

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor, or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

#### **[For OTC only]**

**Read all of this leaflet carefully before you start using this medicine because it contains important information for you.**

Always use this medicine exactly as described in this leaflet or as your doctor or pharmacist have told you.

- Keep this leaflet. You may need to read it again.
- Ask your pharmacist if you need more information or advice.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.
- You must talk to a doctor if you do not feel better or if you feel worse

#### **What is in this leaflet**

1. What PENNSAID is and what it is used for
2. What you need to know before you use PENNSAID
3. How to use PENNSAID
4. Possible side effects
5. How to store PENNSAID
6. Contents of the pack and other information

#### **1. What is PENNSAID and what it is used for?**

PENNSAID is a non-steroidal anti-inflammatory drug (NSAID) commonly used to relieve pain associated with osteoarthritis of a superficial joint (e.g. knee or elbow).

#### **2. What you need to know before you use PENNSAID**

**Do not use PENNSAID:**

- If you are allergic (hypersensitive) to diclofenac, dimethyl sulphoxide (DMSO) or any of the other ingredients of this medicine (listed in section 6).
- If you are pregnant or breast-feeding
- If you have ever had an allergic reaction to acetylsalicylic acid (ASA) or any other NSAID such as ibuprofen with difficulty in breathing, skin rash and runny nose.

## **Warnings and precautions**

Talk to your doctor or pharmacist before using PENNSAID

If you have or had stomach ulcers or a tendency for bleeding or if you are older, tell your doctor or pharmacist before using the solution.

Do not use PENNSAID in joint areas where there is a previous skin disease (e.g. psoriasis) unless advised by your physician.

Please wash your hands after using PENNSAID to avoid contact with eyes, mucous membranes and skin not intended for treatment.

Do not apply PENNSAID if you suffer from liver or kidney problems

Do not cover the treated area with occlusive (waterproof or non breathable) bandages or plasters.

No other medicinal products should be applied to the affected area simultaneously with PENNSAID.

PENNSAID is intended for external use only. If PENNSAID is accidentally swallowed, do not induce vomiting. Seek medical advice immediately.

## **Children**

PENNSAID is not recommended for use in children.

## **Other medicines and PENNSAID**

Tell your doctor or pharmacist if you are taking have recently taken or might take any other medicines.

Especially if you are already using/taking

- Diclofenac tablets or other NSAID pain/inflammation tablets (e.g. aspirin).
- Cardiac glycosides (for example digoxin), used to treat heart problems
- Lithium (used to treat some mental problems)
- Medicines to treat diabetes
- Anticoagulants (blood thinning tablets like warfarin, heparin)
- Diuretics (water tablets)
- Oral steroids (an anti-inflammatory drug)
- Methotrexate (for some inflammatory diseases and some cancers)
- Ciclosporin (used to treat some inflammatory diseases and after transplants)

- Quinolone antibiotics (for infections)
- Medicines used to treat heart conditions or high blood pressure, for example beta-blockers or ACE inhibitors

If you have ever had a reaction (hives, itching or shortness of breath) to dimethyl sulphoxide (DMSO).

## **Pregnancy and breast-feeding**

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

### *Pregnancy*

Do not use PENNSAID if you are pregnant (see section 2 "Do not use PENNSAID")

### *Lactation*

Do not use PENNSAID if you are breast-feeding (see section 2 "Do not use PENNSAID").

## **Driving and using machines**

In the unlikely event that you experience headache, dizziness, light-headedness or confusion after using PENNSAID, do not drive a motor vehicle or operate machinery.

## **PENNSAID contains**

dimethyl sulphoxide which may be irritant to the skin.

## **3. How to use PENNSAID**

### **[For Rx only]**

Always use this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

### **[For OTC only]**

Always use this medicine exactly as described in this leaflet or as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

The application site should be washed with soap and water and allowed to dry before application of PENNSAID. The dose depends on the size of the joint to be treated. Apply 20 to 40 drops four times daily or as advised by your doctor. Do not exceed a maximum of 40 drops, four times per day, per joint. Apply the solution a few drops at a time and spread evenly over the painful area with your hand or fingers. It is not necessary to rub the solution.

After application wash your hands.

## Route of administration

PENNSAID is for cutaneous use only.

## **Use in children**

PENNSAID is not recommended for use in children.

## **4. Possible side effects**

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Minor skin reactions may occur such as skin dryness, tingling, itchiness or rash. Bad breath may also be experienced in some cases.

Other undesirable effects may include constipation, dyspepsia and flatulence. Photoallergic reaction and contact dermatitis have been reported following application of topical diclofenac.

If you develop a skin reaction or any other symptom consult your doctor or pharmacist. In the rare event that you experience wheezy breathing, discontinue treatment and immediately seek medical advice.

PENNSAID is applied to a relatively large area of skin over a prolonged period, the possibility of systemic side-effects similar to systemic effects from oral diclofenac cannot be completely excluded.

Possible systemic side-effects are described as follows:

*Uncommon: may affect up to 1 in 100 people*

- epigastric, gastric, or abdominal pain, abdominal cramps, nausea, dyspepsia, anorexia, diarrhoea, vomiting and flatulence.
- dizziness, headache and vertigo
- elevations ( $\geq 3$  times the upper normal limit) of AST, ALT.

*Rare: may affect up to 1 in 1,000 people*

- gastrointestinal bleeding (bloody diarrhoea, melaena, haematemesis) gastric and intestinal ulcerations with or without bleeding or perforation.
- drowsiness, malaise, impaired concentration and tiredness.
- palpitation, angina and arrhythmias
- urticaria
- liver function disorders including hepatitis with or without jaundice.
- hypersensitivity reaction such as asthma in patients sensitive to ASA e.g., bronchospasm; anaphylactic/anaphylactoid systemic reactions including hypotension.

*Not known: frequency cannot be estimated from the available data*

- lower gut disorders (e.g. non-specific haemorrhagic colitis and exacerbation of ulcerative colitis or Crohn's disease), diaphragm-like intestinal strictures, hyperacidity, stomatitis, glossitis, coated tongue,

oesophageal lesions, constipation and pancreatitis, taste alteration disorders.

- sensory disturbances including paraesthesia, memory disturbance, disorientation, insomnia, irritability, convulsions, depression, anxiety, nightmares, tremor, psychotic reactions and aseptic meningitis
- vision disturbances (blurred vision, diplopia)
- impaired hearing, tinnitus
- exacerbation of cardiac failure and hypertension
- vasculitis
- bullous eruption, erythema, eczema, erythema multiforme, Stevens-Johnson syndrome, Lyell syndrome (toxic epidermal necrolysis), erythroderma (exfoliative dermatitis), loss of hair, the skin may be more sensitive to the sun. Purpura including allergic purpura.
- burning sensation at the application site
- dry skin
- acute renal failure, nephrotic syndrome, urinary abnormalities (e.g. haematuria and proteinuria), interstitial nephritis and papillary necrosis.
- thrombocytopaenia, leukopaenia, agranulocytosis, haemolytic anaemia, aplastic anaemia and anaemia secondary to gastrointestinal bleeding.
- pneumonitis

**PENNSAID contains dimethyl sulphoxide (DMSO) which can cause drowsiness and headache and may be irritant to the skin.**

### **Reporting of side effects**

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the national reporting system listed in [Appendix V](#). By reporting side effects you can help provide more information on the safety of this medicine.

## **5. How to store PENNSAID**

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the label. The expiry date refers to the last day of that month.

Do not store above 25°C. Do not refrigerate.

PENNSAID should not be used for longer than 12 weeks after first opening.

PENNSAID should be a clear, colour-less to pink or orange liquid. If your medicine turns any other colour, return it to your pharmacist.

Do not throw away any medicines via wastewater. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

## **6. Contents of the pack and other information**

### What PENNSAID contains

- The active substance is diclofenac sodium
- Each 1 ml (about 40 drops) of the cutaneous solution contains 16 mg of the active ingredient diclofenac sodium.
- The other excipients are dimethyl sulphoxide (DMSO), ethanol, glycerine, propylene glycol and purified water.

### **What PENNSAID looks like and contents of the pack**

The solution is a clear, colourless to pink or orange liquid.

PENNSAID is dispensed in a soft, opaque, white plastic bottle sealed with a plastic dropper cap.

The product is available in bottle sizes of 15 ml, 30 ml, 60 ml and 150 ml.

Not all pack sizes may be marketed.

### **Marketing Authorization Holder and Manufacturer**

*Marketing Authorisation Holder:*

< To be completed nationally >

*Manufacturer:*

< To be completed nationally >

**This medicinal product is authorised in the Member States of the EEA under the following names:**

AT	Pennsaid 16 mg/ml Lösung zum Auftragen auf die Haut
EL	Pennsaid 16 mg/ml δερματικό διάλυμα
IT	Pennsaid 16 mg/ml soluzione cutanea

**Package Leaflet last revised in <[To be completed nationally]>**